

Appl. No. 09/852,547  
Amdt. Dated October 24, 2006  
Reply to Office Action of April 24, 2006

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### REMARKS/ARGUMENT

#### Status of Claims

Claims 1-94 have been cancelled; new claim 95 has been added to focus the issues in prosecution, without prejudice. Applicant expects to add dependent claims to this application upon a general understanding on the nature and scope of the claim in this response. Support for the amended claims may be found throughout the specification, including [0636] and [0637].

#### Rejections Under 35 U.S.C. § 112, First Paragraph.

In the Office Action, claims 1-6, 12, 17-19, 66, 67, 70-73-76, 81-86 and 89 are rejected under 35 U.S.C. §112, first paragraph for lack of enablement. Applicant thanks the Examiner for the extended discussion of the literature in the field of cancer and hormones. The Examiner is clearly an expert in the area and the Applicant responds as follows. As discussed at length in the rejection the literature and hence the skilled artisan understand the levels of secreted immunoglobulins and the factors with which the skilled artisan would be familiar, viz., common ranges for the secreted immunoglobulins, regardless of the age, gender, etc. of the human subject. What the skilled artisan would not have know, without the present invention, is the critical function these "normal" levels have on epithelial cells exposed to the secreted immunoglobulins (IgA, IgM and IgG1) and their binding to the poly Ig receptor on these cells.

The present invention is based on the recognition that, until cancer cells were grown in serum free medium and exposed to this specific type of secreted immunoglobulins, the effect of these secreted immunoglobulins on estrogen responsiveness and cancer could not have been known. It is a central premise of the present invention that a long-term decrease in the exposure of epithelial cells exposed to secretory immunoglobulin (e.g., breast, prostate, colon, ovary, endometrium, kidney, bladder, stomach, pancreas and secretory pituitary) leads to an increased risk of these cell types becoming cancerous. The present claim captures this central premise as taught in the specification. Applicant points out that secretory component and secreted immunoglobulins are different. Applicant believes that the new claim overcomes the outstanding rejection and respectfully requests allowance of the claim.

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**Rejection under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description, inadequate description of a genus.**

Applicant believes that the claim as amended overcomes the outstanding rejection. The claim as amended focuses the discussion on the specific immunoglobulins at issue without regard to the status of the receptor. Applicant believes that the new claim renders this rejection moot and respectfully requests allowance of the claim.

**Rejection under 35 U.S.C. § 112, first paragraph, New Matter.**

Next, the Action rejects claims 7, 19, 20, 77-79, 86 and 93 under 37 U.S.C. § 112, first paragraph, for New Matter. Support for the present claim may be found in the claims as filed and in the first four paragraphs of the Summary of the Invention. Applicant believes that the new claim overcomes the outstanding rejection and respectfully requests allowance of the claim.

**Rejections Under 35 U.S.C. § 112, First Paragraph, lack of enablement for non-functional receptors.**

Claims 8, 67, 68 and 91 are rejected under 35 U.S.C. § 112, First Paragraph for lack of enablement. Applicant believes that the new claim overcomes the outstanding rejection and respectfully requests allowance of the claim.

**Rejections Under 35 U.S.C. § 112, First Paragraph, lack of enablement for non-functional receptors.**

Claims 7, 12 in part, 13-15, 17 in-part, 18 in part, 19, 69, 71 and 92 are rejected under 35 U.S.C. § 112, First Paragraph for lack of enablement to methods for detecting loss of immunoglobulin regulation of steroid hormone cell growth. Applicant believes that the new claim overcomes the outstanding rejection and respectfully requests allowance of the claim.

**Rejection Under 35 U.S.C. §102, under Harris, et al. "as evidenced by" Cargo, et al.**

Claims 8, 67 and 91 are rejected under 35 U.S.C. §102, under Harris, et al. "as evidenced by" Cargo, et al. Anticipation requires that each and every element of a claimed invention be disclosed in a single reference. Applicant point our that despite the teaching and knowledge of the 1981 Harris reference and the 1978 Cargo reference, the art of predicting cancer has not progressed in

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toward understanding the effect of secreted immunoglobulin on the long-term prognostication of cancer cells. Furthermore, serum-free medium was not known or contemplated by the cited art, as such, the skilled artisan could not have used these to references to obtain the present invention as claimed. Applicant believes that the claim as amended overcomes the outstanding rejection and respectfully requests allowance of the claim.

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**Conclusion**

In light of the amendments, remarks and arguments presented above, Applicant respectfully submits that the claim in the Application is in condition for allowance. Favorable consideration and allowance of the pending Claim 95.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: October 24, 2006.

Respectfully submitted,



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